



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (Monkeypox)

AGENCY: Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Secretary of Health and Human Services (HHS) is issuing this notice pursuant to the Federal Food, Drug, and Cosmetic (FD&C) Act. On August 9, 2022, the Secretary determined pursuant to his authority under the FD&C Act that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad that involves monkeypox virus.

On the basis of this determination, he declared on September 7, 2022 that circumstances exist justifying authorizations of emergency use of in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus*, pursuant to the FD&C Act.

DATES:

The determination was effective August 9, 2022 and the declaration is effective September 7, 2022.

FOR FURTHER INFORMATION CONTACT:

Dawn O'Connell, Assistant Secretary for Preparedness and Response, Administration for Strategic Preparedness and Response, Department of Health and Human Services, 200 Independence Avenue SW., Washington, DC 20201, Telephone (202) 205-2882 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Under section 564 of the FD&C Act, 21 U.S.C. 360bbb-3, the Commissioner of Food and Drugs of the U.S. Food and Drug Administration (FDA), acting under delegated authority from the Secretary of HHS, may issue an Emergency Use Authorization (EUA) authorizing: (1) the emergency use of an unapproved drug, an unapproved or uncleared device, or an unlicensed biological product; or (2) an unapproved use of an approved drug, approved or cleared device, or licensed biological product. Before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of four determinations: (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a, chemical, biological, radiological, or nuclear (“CBRN”) agent or agents; (2) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F-2 of the Public Health Service (PHS) Act^[1] sufficient to affect national security or the health and security of United States citizens living abroad; (3) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces, including personnel operating under the authority of title 10 or title 50, of attack with (i) a biological, chemical, radiological, or nuclear agent or agents; or (ii) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to United States military forces; or (4) a determination by the Secretary that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves a CBRN agent or agents, or a disease or condition that may be attributable to such agent or agents.^[2]

Based on any of these four determinations, the Secretary of HHS may then declare that circumstances exist that justify the EUA, at which point the Commissioner of Food and Drugs may issue an EUA if the criteria for issuance of an authorization under section 564 of the FD&C Act are met.

The ASPR requested that the Secretary issue the declaration to allow the Department to take measures based on information currently available about monkeypox virus. The determination of a public health emergency or a significant potential for a public health emergency, and the declaration that circumstances exist justifying emergency use of in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus* by the Secretary of HHS, as described below, enable the Commissioner of Food and Drugs to issue EUAs for in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus* for emergency use under section 564 of the FD&C Act.

II. Determination by the Secretary of Health and Human Services

On August 9, 2022, pursuant to section 564 of the FD&C Act, I determined that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad that involves monkeypox virus.

III. Declaration of the Secretary of Health and Human Services

On September 7, 2022, on the basis of my August 9, 2022 determination that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad and that involves monkeypox virus, I declared that circumstances exist justifying authorizations of emergency use of in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus*, pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

Notice of the EUAs issued by the Commissioner of Food and Drugs pursuant to this determination and declaration will be provided promptly in the *Federal Register* as required under section 564 of the FD&C Act.

Xavier Becerra,

Secretary,

U.S. Department of Health and Human Services.

Footnotes

1. 42 U.S.C. 247d-6b.
2. As amended by the Pandemic and All-Hazards Preparedness Reauthorization Act, Public Law 113-5, the Secretary may make a determination of a public health emergency, or a significant potential for a public health emergency, under section 564 of the FD&C Act. The Secretary is no longer required to make a determination of a public health emergency in accordance with section 319 of the PHS Act, 42 U.S.C. 247d to support a determination or declaration made under section 564 of the FD&C Act.

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